UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,063	01/28/2002	Norihito Shimono	2002-0055A	8747

513 7590 12/17/2003

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/17/2003

//

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/048,063	Applicant(s) SHIMONO ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response entered 6/4/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is inconsistent and redundant with respect to claims 7. Claim 7 recites an enterically coated dosage form. An enterically coated dosage form by definition would pass through the stomach and have a faster release in the large intestine since it is only releasable in the large intestine.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1, 5, 6, 7, 9,10, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sekigawa et al (USPN 5,217,720 hereafter referred to as '720). The claims are drawn to a

formulation comprising a solid medicament core, coated with a chitosan and enteric polymers. The chitosan is dissolved in water-insoluble polymer.

5. '720 discloses a solid medicament coated with successive layer (abstract). The first layer is a chitosan solution, the next layer(s) comprising enteric polymers (col. 1, lin. 56 – col. 2, lin. 43). The chitosan is dissolved with water-insoluble polymers and spray-dried onto the solid core (col. 4, lin. 67 – col. 5, lin. 19). The polymers are listed as cellulose derivatives. The chitosan-coated medicament is next coated with enteric polymers such as hydroxypropyl methylcellulose acetate succinate (col. 5, lin. 32 – 45). The enteric coating by definition does not dissolve in the stomach as passes though releasing in the intestinal tract. These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 2-4, 8 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Sekigawa et al (USPN 5,217,720 hereafter referred to as '720) and Suzuki et al (USPN 5,283,064 hereafter referred to as '064). The claims are drawn to a formulation comprising a solid medicament core, coated with a chitosan and enteric polymers. The chitosan is dissolved in water-insoluble polymer.

9. As discussed above '720 discloses a solid medicament coated with chitosan and enteric polymers. What is lacking in the reference is a disclosure of the particular water-insoluble polymers recited in the instant claims. '064 discloses a solid medicament comprising chitosan dissolved in water-insoluble polymers (col. 2, lin. 38 – 480. The water-insoluble polymers include ethyl cellulose, methacrylic acid-methyl methacrylates copolymer and others well know in the art (col. 3, lin. 9 – 55). A skilled artisan would have been motivated to follow the suggestion of '720 and include the polymers of '064 in order to improve the release of the medicaments.

With regard to claims 4, 11 and 12 it is the position of the examiner that such limitations do not impart patentability on the formulation, barring a showing of criticality. The combination of the prior art discloses a solid medicament coated in succession with chitosan dissolved in water-insoluble polymers and enteric polymers. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having

various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to claims 1, 8 and their subsequent dependent claims, these claims are considered product by process claims. The prior art provides a coated medicament where the coating comprises chitosan, water-insoluble polymers and enteric polymers. The limitation that the preparations are "produced by coating a medicament..." does not impart patentability over the prior art, since the claims are drawn to a product. The process by which a product is made is irrelevant when a product is claimed. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

10. With these things in mind a skilled artisan would have been motivated to follow the suggestions of '720 and include the polymers of '064 into a combination in order to improve the release of the medicament once the table reached the intestinal tract. Specific release would be determined via selection of enteric polymers and ratios, which is well within the level of skill in the art to determine through routine experimentation. It would have been obvious to combine the suggestions and teachings of the prior art in such a sway with an expected result of an enterically coated tablet comprising chitosan releasable in the intestinal tract.

Response to Arguments

11. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-746-7648.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600